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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,544	12/14/2005	**Breda Mary Cullen**	101713-5033	6443

28977 7590 10/05/2010

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
10/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,544	CULLEN ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-13 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-13 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 17, 2010 has been entered.

Terminal Disclaimer

2. The terminal disclaimer filed on June 17, 2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application No. 10/579897 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1 – 3 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 9 and 12

of copending Application No. 11/608553 in view of Partain et al. (EP 0368253). The claims of US'553 recited a wound dressing composition comprised of human recombinant collagen and oxidized cellulose (claim 1) or oxidized regenerated cellulose (claim 4). The wound dressing composition can also contain one or more wound healing therapeutic substances (claim 9).

US'553 does not disclose the inclusion of an antioxidant dyestuff as required by the instant claims.

Partain et al. discloses delivery systems containing pharmaceutical and therapeutic actives which be administered to a desired topical or mucus membrane site (col 2, ln 14 – 17). The ingredients can be fabricated into films, rods, sheets, sponges or fibers for use as medicated sutures, medicated sheets, medicated bandages, patches and the like (col 12, ln 31 – 37). A wide variety of pharmaceutical or therapeutic actives can be delivered with this system, including acridine dyes as an antiseptic (col 9, ln 38 – 41; col 10, ln 12).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate acridine dyes into the human collage and oxidized cellulose wound dressing compositions of US'553. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Partain et al. discloses that wound dressing compositions can contain and deliver therapeutic agents like the antiseptic acridine dyes, resulting in a wound dressing compositions comprising oxidized cellulose and antimicrobial antioxidant dyestuffs such as the acridine dyes as recited in the instant claims.

This is a provisional obviousness-type double patenting rejection.

Applicants traverse this rejection on the grounds that the examples indicate sustained dye release but the cited references do not demonstrate the production of such a composition. The combination also does not result in material in which the dyestuff is bound to the surface. These arguments are unpersuasive. The examples indicate that incorporation of the dye into the material will result in the same composition and the structure of the formulation will determine the release rate of the antioxidant dyestuff. Contact between the support material and the dye results in surface binding of the material and so upon incorporation of the acridine dye into the composition of US'553 will result in antioxidant bound to the surface.

Applicant also argue that "dyed" refers to a solid material that bas been surface treated while in the solid state with a dye to bind the dye and Partain does not teach such a composition. These arguments are unpersuasive. The instant claims are products and as such, "dyed" is a product-by-process limitation. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**. Applicants have not presented any evidence as to the different product that results from incorporation of the dye into the composition in the solid, rather than liquid, state.

Response to Arguments

5. Applicant's arguments with respect to the rejection of claims 1, 5 – 13 and 20 based upon Partain et al. in view of Rosenthal et al. have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 5, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. (EP 0368253) in view of Britton et al. (US 2003/0007957) and/or Cullen et al. (Intl J Biochem Cell Bio, 2002).

Partain et al. discloses delivery systems containing pharmaceutical and therapeutic actives administered to a desired topical or mucus membrane site (col 2, ln 14 – 17). The delivery system comprises aminopolysaccharides including chitosan derivatives (col 2, ln 33 – 35). The ingredients can be fabricated into films, rods, sheets, sponges or fibers for use as medicated sutures, medicated sheets, medicated bandages, patches and the like (col 12, ln 31 – 37). A wide variety of pharmaceutical or therapeutic actives can be delivered with this system, including acridine dyes as an antiseptic (col 9, ln 38 – 41; col 10, ln 12).

Partain et al. does not disclose oxidized cellulose as the solid bioabsorbable substrate.

Britton et al. discloses a wound care preparation for topical or surgical wounds for use in wound care (abstract). The structural matrix can be made using chitosan or oxidized regenerated cellulose.

Cullen et al. discloses that a wound treatment using oxidized regenerated cellulose (ORC) and collagen biomaterial (p 1545, col 2, ¶ 2). This material scavenges free radicals as compared to other biopolymers (p 1550, Section 3.4). ORC/collagen binds and inactivates the proteases present in chronic wound fluid (p 1554, col 1). Free radicals can also contribute to and potentially inhibit healing in chronic wounds (p 1555, col 1, ¶ 2). A DPPH test was used to determine the ability of the ORC/collagen material to scavenge free radicals (p 1547, Section 2.5). Based on these and other factors, the ORC/collagen material can have a beneficial effect in the treatment of wound (p 1555, col 1, last sentence).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the ORC/collagen material of Cullen et al. in the delivery system described by Partain et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Britton et al. discloses that oxidized cellulose and chitosan, the substrate material used by Partain et al., are functionally equivalent materials that can be used as solid substrates for wound care materials. In addition, the use of ORC in the delivery platform provides a number of benefits to the wound, including scavenging of free radicals and protease inactivation, as taught by Cullen et al.

10. Claims 1, 5 – 7, 11, 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Britton et al., Cullen et al. as applied to claims 1, 5, and 20 above, and further in view of Shanbrom (US 6,361,786).

As discussed in greater detail above, Partain et al., Britton et al. and/or Cullen et al. disclose a wound dressing material that delivers a therapeutic agent such as the antiseptic acridine dye wherein the use of ORC/collagen substrate that provides additional benefits in wound healing. Scavenging of radicals is among the features of the ORC/collagen that provides these wound healing. Free radical activity was measured using the DPPH test for antioxidant activity (Section 2.5 of Cullen et al.). The dressing material can take a variety of forms, including sheets (col 12, ln 37 of Partain et al.).

None of the references disclose a specific dye as recited in claim 7. Partain et al. only discloses the genus of "acridine dyes".

Shanbrom discloses microbicide polymeric treated materials (abstract). A variety of organic dyes can be used, including methylene blue, thionine dyes, acridine orange, acridine yellow, brilliant green, crystal violet (gentian violet) or trypan blue (col 2, ln 33 – 40). To make these materials antimicrobial, gloves were soaked in a 1% total (0.5% gentian violet; 0.5% methylene blue; col 4, ln 66 – col 5, ln 2) of dye.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use one of the specific dye disclosed by Shanbrom in the wound dressing materials of Partain et al., Britton et al. and Cullen et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Shanbrom discloses that these particular dyes are antimicrobial/antiseptic therapeutic agents that can be delivered using the delivery system of Partain et al. with the additional wound care benefits of the

ORC/collagen substrate material. Cullen et al. also discloses that free radical scavenging has beneficial effects in wound care so the person of ordinary skill in the art would optimize the free radical scavenging activity and the antiseptic/antimicrobial activity of the material provide by the acridine dyes. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results of free radical scavenging and antimicrobial activity to promote wound healing.

11. Claims 1, 5 – 11, 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Britton et al., Cullen et al. and Shanbrom as applied to claims 1, 5 – 7, 11, 13 and 20 above, and further in view of Nimrod et al. (WO 87/05517).

As discussed in greater detail above, Partain et al., Britton et al. and/or Cullen et al. disclose a wound dressing material that delivers a therapeutic agent such as the antiseptic/microbicide dyes such as methylene blue or trypan blue wherein the use of ORC/collagen substrate that provides additional benefits in wound healing. Scavenging of radicals is among the features of the ORC/collagen that provides these wound healing.

None of the references disclose the inclusion of a silver salt in the dressing material.

Nimrod et al. teaches heavy metal salts of hyaluronic acid, an anionic polymer where the heavy metal can be silver (p 4, ln 27). Silver ions are effective antimicrobial agents without significant side effects that are rarely associated with silver antibiotic-resistant strains of bacteria. Silver salts are useful as topical anti-infectives or antiseptics (p 3, ln 7 – 13).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a silver salt into the wound dressing material. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because oxidized regenerated cellulose is also anionic that will bind silver ions to provide an additional antiseptic action. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**. Both silver ions and antioxidant dyestuffs have antimicrobial/antiseptic properties but exert their antimicrobial activity via different mechanisms.

12. Claims 1, 5 – 7, 11 - 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Britton et al., Cullen et al. and Shanbrom as applied to claims 1, 5 – 7, 11, 13 and 20 above, and further in view of Gibbins (US 6,255,858).

As discussed in greater detail above, Partain et al., Britton et al. and/or Cullen et al. disclose a wound dressing material that delivers a therapeutic agent such as the antiseptic/microbicide dyes such as methylene blue or trypan blue wherein the use of ORC/collagen substrate that provides additional benefits in wound healing. Scavenging of radicals is among the features of the ORC/collagen that provides these wound healing.

None of the references discloses a sterile material packaged into a microorganism-impermeable container.

Gibbins teaches wound dressings that administer an active agent (col 4, ln 8 – 11). The matrix material can be cut from a sheet and sterilized by a number of methods (col 12, ln 52 – 65).

It would have been obvious to one of ordinary skill in the art with a reasonable expectation of success to take the wound dressing composition of Partain et al., Britton et al. and Cullen et al. and sterilize the wound dressing material as taught by Gibbins. Once sterile, it would be obvious to place the sterile material in a container or packaging to maintain the sterility of the matrix ("microorganism-impermeable container"). After having removed any potential microbial contamination from the wound dressing by sterilization, packaging that will prevent contamination prior to use, when microbial contamination is undesirable, the packaging can be used to maintain that sterility.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nissa M Westerberg/
Examiner, Art Unit 1618